

4179-123

Section II (Remarks)**RECEIVED
CENTRAL FAX CENTER****AUG 07 2006****A. Summary of Amendments To The Claims**

By the present amendment, claims 1-14, 16-49 and 51 have been canceled (claim 15 was canceled previously), and dependent claims 53-56 have been added, such that claims 50 and 52-56 are currently pending in the application. No new matter within the meaning of 35 U.S.C. 132(a) has been added.

B. Claim Rejections

In the June 5, 2006 Office Action, claims 1-14, 29-39, 43, 44, and 50 were rejected on various grounds over various references and/or combinations thereof, including:

- a rejection of claims 1-4, 6, 9, 12-14, 29-32, 34-35, and 37 under 35 USC §103(a), as being unpatentable over U.S. Patent No. 6,136,011 to Stambaugh ("Stambaugh") in view of U.S. Patent No. 4,668,224 to Lentz et al. ("Lentz");
- a rejection of claims 1-5, 8, 10, 12-14, 29-33, 36, and 38 under 35 USC §103(a), as being unpatentable over U.S. Patent No. 4,338,942 to Fogarty ("Fogarty") in view of Lentz;
- a rejection of claims 1-4, 6-8, 12-14, 29-32, 34-36, 43-44, 50, and 52 under 35 USC §103(a), as being unpatentable over U.S. Patent No. 6,746,465 to Diederich ("Diederich") in view of Lentz; and
- a rejection of claims 11 and 39 under 35 USC §103(a), as being unpatentable over Stambaugh, Fogarty, or Diederich in view of Lentz in further view of U.S. Patent No. 5,512,051 to Wang ("Wang").

The rejections as to claims 1-14, 16-49 and 51 are moot in view of the cancellation of those claims. The rejections as to claims 50 and 52 are traversed, as detailed below.

1. Law Regarding Rejections Under 35 USC § 103(a)

4179-123

Concerning §103 obviousness rejections, three requirements must be met for a *prima facie* case of obviousness. First the prior art reference(s) must teach all of the limitations of the claims: M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on applicant's disclosure. M.P.E.P. § 2143.

Furthermore, a basic consideration, which applies to all obviousness rejections, is that references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination. MPEP 2141.02.

2. Failure of the Cited References to Support a Prima Facie Case of Obviousness As to the Pending Claims

Claims 50 and 52-56 comprise one independent claim - namely, claim 50. Claim 50 is directed to "[a] method for controlling post-partum hemorrhage" and recites, *inter alia*:

"inserting [a] balloon catheter apparatus into at least one of an internal uterine wall area and a vaginal wall area; and inflating the first balloon with a gaseous medium so as to apply a substantially even pressure over the at least one wall area for reducing or eliminating bleeding therein."

Neither Diederich nor Lentz cited by the examiner as the basis for rejecting claim 50 discloses such limitations. Lentz is cited disclosing the use of oxidized cellulose as a lubricant to ease introduction of a catheter device. Diederich does disclose a multi-lumen catheter shaft having multiple balloons attached thereto, but Diederich fails to teach or suggest any method for controlling hemorrhage. Instead, Diederich teaches the use of a balloon catheter device for positioning and/or shielding non-target tissues and organs during treatment (e.g., thermal, acoustic, or radiation treatment) of a target tissue. See Diederich, col. 6, lines 54-56 "[t]he apparatus is particularly suited to protect sensitive tissues for thermal or acoustic treatments;" and col. 10, lines 15-18 "the catheter 10 [is placed] at the boundary of the treatment site and the healthy tissue or sensitive tissues or structures that may be damaged during treatment of the target tissues."

4179-123

In one example, Diederich further discloses a multi-balloon embodiment adapted for "sequential inflation" to provide planar separation of target and non-target tissues. *Id.*, col. 9, lines 34-40.

In another example, Diederich discloses "insertion of the catheter in the space between the prostate and the rectum" to "physically separate the thermal and radiation sensitive rectum tissue from the prostate gland being treated" such that the "fluid filled balloon may act as a heat sink to draw heat away from the sensitive tissues." Diederich, col. 4, lines 52-59.

None of the treatment methods disclosed in Diederich contemplate laceration or abrasion of tissues that would give rise to a bleeding problem. Clearly, inflating a balloon catheter device within a uterus or vagina to apply pressure to a wall thereof (e.g., to control hemorrhage) will not serve to "reposition an organ," since the position of these uterine and vaginal structures are fixed. Diederich teaches that the device may be used interstitially as well as laproscopically (e.g., involving use of a fiber optic for visual examination) or endoscopically (e.g., for visualizing the interior of a hollow organ). See Diederich, col. 6, lines 50-52. While Diederich does mention interstitial, laproscopic, or endoscopic use of a catheter device for procedures in the uterus/cervix (col. 6, lines 50-52), **nothing in Diederich suggests that the catheter device is useful for "applying] substantially even pressure over the at least one wall area for reducing or eliminating bleeding therein"** as required by claim 50.

Accordingly, since any combination of Diederich and Lentz fails "to teach all of the limitations of the claim" as required by M.P.E.P. § 2143.03 to support any *prima facie* case of obviousness of the claim, the rejection of claim 50 under 35 USC § 103 cannot stand. Withdrawal of such rejection is respectfully requested.

Since dependent claims inherently include all the limitations of claims on which they depend, claims 52-56 are likewise patentably distinct over any combination and Diederich and Lentz.

C. (No) Fees Payable For Added Claims

By the present Amendment, Applicants have canceled a total of 49 claims, and have added four dependent claims. Since the total number of pending claims has not increased by virtue of the present amendment, no excess claim fees are due and payable with the present Response.

D. Consideration of Enclosed Information Disclosure Statement

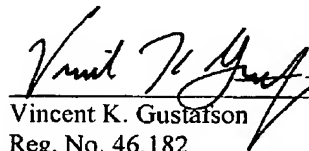
A Supplemental Information Disclosure Statement is enclosed herewith for consideration by the Examiner.

Conclusion

Claims 50 and 52-56 as now pending in the application have been patentably distinguished over the cited references, and are in form and condition for allowance. Issuance of a Notice of Allowance for all of these claims in the application is therefore requested.

If any issues remain outstanding, incident to the formal allowance of the application, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss them so as to avoid delays in prosecution.

Respectfully submitted,



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Enclosures:

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Credit Card Payment Form PTO-2038 Authorizing \$180.00

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